

Declaration of Conformity

as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Manufacturer: Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Roche Diagnostics GmbH declares that the product/the product line

Product name: VENTANA HER2 Dual ISH DNA Probe Cocktail

Roche Id.-No.: 08314373001

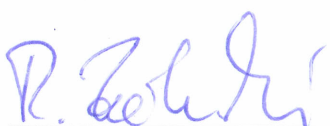
Ventana Id.-No.: 800-6043

to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 16 April 2019

Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

i.V. Stefan Grigarczik



Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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